IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:	**Confirmation No.:** 4498
Robert J. Garabedian, et al.	**Group Art Unit:** 3739
Serial No.: 10/606,250	**Examiner:** Peffley, Michael F.
Filed: June 24, 2003	
For: METHOD OF GENERATING A COMPOUND LESION	

APPEAL BRIEF-CFR 41.37

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Brief is in furtherance of the Notice of Appeal filed January 30, 2006, and contains the following items in the order indicated below as required by C.F.R. §41.37:

I. Real Party in Interest
II. Related Appeals and Interferences
III. Status of Claims
IV. Status of Amendments
V. Summary of Claimed Subject Matter
VI. Grounds of Rejection to be Reviewed on Appeal
VII. Arguments
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I. Real Party in Interest

The real party in interest in this appeal is Scimed Life Systems, Inc., a corporation organized under the laws of Minnesota.

II. Related Appeals and Interferences

There are no appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. Status of Claims

This application includes claims 1-81. Of these claims, claims 23-29, 33-44, 48, 49, and 70-81 are pending, and the remaining claims 1-22, 30-32, 45-47, and 50-69 have been cancelled. All pending claims stand rejected, leaving no claims allowed. The claims on appeal are claims 23-29, 33-44, 48, 49, and 70-81.

IV. Status of Amendments

All amendments have been entered.

V. Summary of Claimed Subject Matter

In its broadest sense, the invention, as defined in the claims on appeal, is directed to a method of guiding one or more ablation probes through different apertures of an alignment device to create compound tissue lesions. In this manner, the ablation probe(s) can be indexed, so that proper placement of the ablation probe(s) relative to the tissue can be efficiently and accurately performed. It has been recognized by the inventors that this method addresses situations where visualization of the ablation probe(s) within the patient's body is difficult to attain, e.g., when ultrasound visualization

of the ablation probe(s) is obscured by an echogenic cloud resulting from previous tissue ablations. Although it should not be limited to the preferred methods described in the specification, the invention will now be described in terms of the preferred methods in order to aid in further understanding the invention.

Figs. 14-17 illustrate one method of using a single ablation probe to produce a compound tissue lesion within a tumor. First, an alignment device 140 is affixed relative to the target tissue, and in particular, is adhered directly to the skin of the patient (page 21, lines 8-12; Fig. 14). Next, the probe assembly 110, which includes a cannula 114 and an electrode array 126 deployable therefrom, is guided through an aperture 150 within the alignment device 140 and into the patient until the distal end 122 of the cannula 114 is adjacent a first target site TS1 within the tumor T (page 21, line 13 to page 22, line 2; Fig. 15). Then, the electrode array 126 is deployed from the cannula 114 into the first target site TS1, and electrical energy is delivered from the electrode array 126 to create a lesion coincident with the first target site TS1 (page 22, lines 3-12; Fig. 16). Next, the probe assembly 110 is removed from the first aperture 152 and guided through a second different aperture 152 within the alignment device 140 to place the distal end 122 of the cannula 114 adjacent a second target site TS2, and electrical energy is again delivered from the electrode array 126 to create a lesion coincident with the second target site TS2 (page 22, lines 13-17; Fig. 17). The process is performed using other apertures 152 within the alignment device 140 until the entire treatment region TR is ablated (page 22, lines 17-18).

Fig. 18 illustrates one method of using multiple ablation probes to produce a compound tissue lesion within a tumor. The probe assemblies 110 are guided through

respective apertures 152 within the alignment device 140 and into the patient until the distal ends 122 of the cannulae 114 are adjacent the respective target sites TS within the tumor T, and the electrode arrays 126 are deployed from the cannulae 114 into the target sites TS (page 23, lines 9-13). Then, electrical energy is delivered sequentially from the electrode arrays 126 or sequentially between pairs of electrode arrays 126 to create lesions in the treatment region TR (page 23, lines 13-20).

VI. Grounds of Rejection to be Revealed on Appeal

A. Whether claims 23-27, 29, 33-39, 44, 48, 49, and 70-81 are unpatentable under 35 U.S.C. §103 as being obvious over U.S. Patent No. 6,530,922 issued to Cosman, et al. ("Cosman").

B. Whether claims 28 and 40-43 are unpatentable under 35 U.S.C. §103 as being obvious over Cosman, in view of U.S. Patent Publication No. 2002/0120261 to Morris, et al. ("Morris").

VII. Arguments

A. Claims 23-27, 29, 33-39, 44, 48, 49, and 70-81

Appellant respectfully submits that the Examiner erred in rejecting claims 23-27, 29, 33-39, 44, 48, 49, and 70-81 under 35 U.S.C. §103 as being obvious over Cosman.

1. Claims 35-38, 44, 48, 49, 72, 73, and 81

As the Examiner has pointed out, Cosman fails to disclose the "sequential operation of the probes," as required by independent claim 35. However, the Examiner concludes that Cosman specifically teaches that it was known to provide for the creation of individual lesions and to provide sequential heating with various probes, and

that it would have therefore been obvious to modify the Cosman method to serially or sequentially activate multiple probes to create multiple lesions in tumor tissue.

While Appellant does not disagree that it was known to serially or sequentially activate multiple probes to create multiple lesions (see background of present application), Appellant does disagree that one of ordinary skill in the art would have been motivated to modify the Cosman method in the manner suggested by the Examiner.

It is established principle that "a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." (See M.P.E.P. §2141.02). A reading of Cosman, as a whole, would suggest to one of ordinary skill in the art that ablation energy should only be simultaneously delivered to electrodes that have been guided through a stereotactic guide to operate as a single larger electrode, and that Cosman merely recognized the existence of the sequential activation of multiple electrode as a comparison to the preferred method. There is simply no suggestion in Cosman that such preferred method be replaced with the prior art method.

In particular, besides emphasizing that the ablation energy should be simultaneously (as opposed to serially or sequentially) delivered to the cluster of electrodes, Cosman repeatedly states that simultaneous delivery of ablation energy to the cluster of electrodes allows the electrode cluster to become a larger, coherent electrode, so that the heating effect is similar to that accomplished by a single electrode (see col. 3, line 63 to col. 4, line 5; col. 6, lines 50-57; col. 7, lines 23-26; col. 8, lines 32-40). The preferred method disclosed in Cosman was merely meant to replace

previous ablation methods that utilize a single larger ablation probe—not to create compound lesions. Thus, when Cosman mentioned the prior art step of sequentially delivering ablation energy to electrodes, Cosman was merely comparing it to simultaneously delivering ablation energy to electrodes, and emphasizing that the latter step is to be implemented in the Cosman method—i.e., ablation energy is to be simultaneously delivered to electrodes that have just been guided through a stereotactic guide. Cosman was not disclosing an alternative method, but rather was teaching away from the sequential delivery of ablation energy to the guided electrodes.

As such, Cosman does not suggest to one of ordinary skill in the art that the stereotactic device disclosed in Cosman be used to generate compound lesions—but quite the opposite—a single larger lesion. In contrast, Appellant has invented a method for accurately and efficiently creating compound lesions, so that the physicians need not estimate the initial location of the ablation probes, thereby minimizing or obviating the need to reposition the ablation probes—especially when addressing difficulty related to reduced ultrasonic image visualization caused by the echogenic cloud produced by previous ablations. Cosman does not suggest modifying the disclosed method for this purpose or any purpose.

Thus, Appellant respectfully believes that claims 35-38, 44, 48, 49, 72, 73, and 81 are patentable over Cosman.

2. Claims 23-26, 29, 33, 34, and 78

As the Examiner has pointed out, Cosman fails to disclose "providing a first probe in a first aperture to create a first lesion, then removing the probe and placing it in a different aperture to create a second lesion," as required by independent claim 23.

However, the Examiner concludes that Cosman specifically teaches that it was known to provide for the creation of individual lesions and to provide sequential heating with various probes, and that it would have therefore been obvious to modify the Cosman method to serially or sequentially activate a single probe to create multiple lesions in tumor tissue.

While Applicant does not disagree that it was known to serially or sequentially activate a single probe to create multiple lesions (see background of present application), Applicant does disagree that one of ordinary skill in the art would have been motivated to modify the Cosman method in the manner suggested by the Examiner. Again, a reading of Cosman, as a whole, would suggest to one of ordinary skill in the art that ablation energy should only be simultaneously delivered to electrodes that have been guided through a stereotactic guide to operate as a single larger electrode.

In addition, nowhere does Cosman disclose, teach, or suggest that the same ablation probe can be guided through different apertures in the stereotactic device to create a compound lesion in the manner required by independent claim 23. Not only does Cosman fail to suggest the sequential delivery of ablation energy to variously located ablation probes, the entire disclosure of Cosman revolves around the formation of electrode arrays by guiding multiple electrodes through an alignment device, thereby seemingly excluding, or at the least teaching away from, any methodology wherein the same ablation probe is guided through different apertures in an alignment device. The title of the Cosman patent, i.e., Cluster Ablation Electrode Systems, evidences this.

Thus, Appellant respectfully believes that claims 23-26, 29, 33, 34, and 78 are patentable over Cosman.

3. Claims 70, 71, 74, and 75

Claims 70, 71, 74, and 75, which depend from independent claims 23 and 35, provide additional patentable features not disclosed, taught, or suggested in Cosman. In particular, claims 70 and 74 require the ablation probe(s) to include a cannula with at least one electrode deployable within the first and second regions. Claims 71 and 75 further require the electrode(s) to include a plurality of tissue-piercing electrode tines configured to be deployed radially outward. Significantly, not only does Cosman fail to suggest the use of cannulae with deployable electrodes, such a modification would defeat the objective set forth in Cosman.

It is an established principle that if a proposed modification would render the prior art device or method being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. (See M.P.E.P. §2143.01). In the present case, Cosman describes several problems associated within the use of cannulae with deployable electrodes and attempts to solve these problems with the disclosed method. In particular, these problems include hemorrhaging caused by the relatively large diameter cannula and multiple passes of the electrodes, as well as the irregularities and undulations in the resulting lesion shape. Cosman states:

> A severe hazard of multiple extrusion of side-outlet electrodes is that it produces hemorrhaging by the multiple passes of the side outlet electrodes near the central cannula. Also, at the periphery of such side-emitting electrode lesions, irregularities and undulations in lesion shape and inhomogeneities in temperature around the side-emitted electrode tips produce hot and cold spots over the lesion volume. These may cause focal boiling and charring of tissue with unpredictable and dangerous

> consequences. For example, consider a large tumor of about 3 to 4 cm diameter in the liver. In such an example, there is a further risk that such undulations and variations in the shape of the periphery of the heat ablation zone would cause portions of the cancerous tumor to be missed by the heat ablation, which of course, would result in continued tumor growth and progression of cancer. Further, a single central cannula, which has one or many side-emitting radiofrequency electrode tips has a diameter, which increases with the number of radiofrequency tips that emerge from it. When the diameter reaches 3 to 4 mm for such a central cannula, there is the disadvantage of increased risk of hemorrhage and/or great pain or discomfort to the patient during insertion of the large central cannula into the tissue. (col. 3, lines 7-29)

To address these problems, Cosman emphasizes the insertion of very small needle electrodes through the apertures of a stereotactic guide, rather than using a large cannula with a plurality of deployable needle electrodes, and simultaneously applying RF energy to the electrodes, stating:

> Contrary to existing electrode configurations and techniques, which propose inserting one large electrode into body tissue, thereby often causing severe hemorrhage, the present system of coherent cluster electrodes inserts into body tissue, multiple independent rigid electrode shafts of the cluster, each of appropriate small diameter, which reduces the risk of hemorrhage. The problem of irregular lesion ablation zones and inhomogeneities of ablation regions associated with prior side-emitting electrodes is also avoided by the coherent cluster electrodes of the present invention. (col. 4, lines 12-22).
>
> Yet another advantage of the coherent cluster electrode system of the present invention is that in accordance with one embodiment it enables all its electrodes to be inserted in unison and in a known geometric relationship to one another. In one embodiment, each electrode may be configured with a small shaft with a pointed, self-penetrating tip. Accordingly, the chance of a hemorrhage occurring from a multiple cluster of such smaller electrodes is less likely than with a single electrode of larger diameter. Even if the cluster of electrodes is not inserted in a precisely parallel fashion, the effect of their coherence in making a larger lesion volume is still effective. (col. 4, line 58 to col. 5, line 2).
>
> An advantage of a multiplicity of coherent smaller electrodes versus insertion of a single large electrode is that the smaller electrodes will produce less chance of hemorrhage. The arrangement of their geometry

> may also be tailored to the clinical application. Insertion of several small gauge electrodes is less painful, uncomfortable, and risk-inducing than insertion of one large, equivalent radiofrequency electrode. For example, insertion of a cluster of several 18 gauge or 1.25 mm diameter pointed radiofrequency electrodes into the liver produces very low risk of hemorrhage and low discomfort. Insertion of an equivalent, but much larger single electrode, which may have a diameter of, for example, 0.25" or 6.4 mm, would have a higher risk of hemorrhage and would be very uncomfortable for the patient if the electrode were inserted percutaneously. (col. 9, line 57 to col. 10, line 4).

Thus, it can be appreciated from a reading of the entire disclosure that there is no suggestion in Cosman, and in fact a teaching against, guiding a cannula with deployable electrodes through the apertures of the stereotactic device. Thus, an additional reason as to why claims 70, 71, 74, and 75 are patentable over Cosman is provided.

4. Claims 76, 77, 79, and 80

Claims 76, 77, 79, and 80, which depend from independent claims 23 and 35, provide additional patentable features not disclosed, taught, or suggested in Cosman. In particular, claims 76 and 79 require the alignment device be affixed to the skin of the patient, and claims 77 and 80 require the alignment device be bonded to the patient. Significantly, not only does Cosman fail to suggest the affixation of the alignment device to the patient's skin, Cosman teaches away from this. That is, Cosman teaches introducing a plurality of small needles directly into an organ (see Fig. 1 and col. 6, lines 50-63). If the alignment device disclosed in Cosman were to be applied to the patient's skin, the small needles would not be suitable for percutaneous treatment of tumors. Thus, an additional reason as to why claims 76, 77, 79, and 80 are patentable over Cosman is provided.

B. Claims 28 and 40-43

Appellant respectfully submits that the Examiner erred in rejecting claims 28 and 40-32 under 35 U.S.C. §103 as being obvious over Cosman in view of Morris. In particular, as discussed above, Cosman does not disclose, teach, or suggest the activation of the same ablation probe guided through different apertures of an alignment device or the sequential activation of ablation probes that have been guided through respective apertures of an alignment device, and Morris does not supplement this failed teaching. Thus, Appellant respectfully believes that claims 28 and 40-43 are patentable over the combination of Cosman and Morris.

Respectfully submitted,

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VIII. Appendix of Claims Involved in the Appeal

23. A method of using an alignment device for performing a compound ablation in the body of a patient, the alignment device having a plurality of apertures, comprising:

affixing an alignment device relative to targeted tissue, wherein the apertures are located external to the body;

guiding an ablation probe within a first one of the externally located apertures to place the ablation probe adjacent the targeted tissue in a first region;

operating the ablation probe to create a first lesion in the first region;

guiding the ablation probe within a second different one of the externally located apertures to place the ablation probe adjacent the targeted tissue in a second region; and

operating the ablation probe again to create a second lesion in the second region.

24. The method of claim 23, further comprising completely removing the ablation probe from the first aperture prior to guiding the ablation probe within the second aperture.

25. The method of claim 23, wherein alternate guiding and operating of the ablation probe is performed for a plurality of regions until the entire target tissue is ablated.

26. The method of claim 23, wherein the ablation probe is guided within the first and second apertures in parallel directions.

27. The method of claim 23, wherein the ablation probe is guided within the first

and second apertures in non-parallel directions.

28. The method of claim 23, wherein the alignment device comprises a boss or a recess associated within the first aperture, the method further comprising modifying a distance that the ablation probe is guided within the first aperture by abutting a portion of the ablation probe against the boss or recess.

29. The method of claim 23, wherein the ablation probe is operated by generating RF energy to create the first and second lesions.

33. The method of claim 23, wherein the ablation probe is percutaneously guided within the first and second apertures into the body of the patient.

34. The method of claim 23, wherein the target tissue is a tumor.

35. A method of using an alignment device for performing a compound ablation in the body of a patient, the alignment device having a plurality of apertures, comprising:

affixing an alignment device relative to targeted tissue, wherein the apertures are located external to the body;

guiding a plurality of ablation probes within respective ones of the externally located apertures to place the ablation probes adjacent the targeted tissue in a plurality of regions, and

sequentially operating sets of the ablation probes to create a plurality of lesions in the plurality of regions.

36. The method of claim 35, wherein the plurality of ablation probes are operated by transmitting RF energy between at least two of the ablation probes.

37. The method of claim 35, wherein the entire target tissue is ablated.

38. The method of claim 35, wherein the ablation probes are guided within the plurality of apertures in parallel directions.

39. The method of claim 35, wherein the ablation probes are guided within the plurality of apertures in non-parallel directions.

40. The method of claim 35, wherein the alignment device comprises one or more bosses or recesses associated within one or more of the plurality of apertures, the method further comprising modifying a distance that one or more of the ablation probes are guided within one or more of the plurality of apertures by abutting a portion of the one or more ablation probes against the one or more bosses or recesses.

41. The method of claim 40, wherein the one or more bosses or recesses comprises a plurality of bosses or recesses.

42. The method of claim 41, wherein the bosses or recesses have differing lengths.

43. The method of claim 40, wherein one or more bosses or apertures is associated with one or more inserts, wherein one or more inserts are removably mounted.

44. The method of claim 35, wherein the ablation probes are operated by generating RF energy to create the plurality of lesions.

48. The method of claim 35, wherein the ablation probes are percutaneously guided within the plurality of apertures into the body of the patient.

49. The method of claim 35, wherein the target tissue is a tumor.

70. The method of claim 23, wherein the ablation probe has a cannula and at least one electrode deployable from the cannula, the method further comprising

deploying the at least one electrode from the cannula into the first region prior to creating the first lesion and deploying the at least one electrode from the cannula into the second region prior to creating the second lesion.

71. The method of claim 70, wherein the at least one electrode comprises a plurality of tissue-piercing electrode tines configured to be deployed radially outward.

72. The method of claim 35, wherein each probe set comprises a single probe.

73. The method of claim 35, wherein each probe set comprises a pair of probes.

74. The method of claim 35, wherein each of the plurality of ablation probes has a cannula and at least one electrode deployable from the cannula, the method further comprising deploying the at least one electrode from each cannula into a respective one of the plurality of regions prior to creating a lesion in the respective region.

75. The method of claim 70, wherein the at least one electrode of each ablation probe comprises a plurality of tissue-piercing electrode tines configured to be deployed radially outward.

76. The method of claim 23, wherein the alignment device is affixed to skin of the patient.

77. The method of claim 23, wherein the alignment device is bonded to the patient.

78. The method of claim 23, wherein the alignment device is planar.

79. The method of claim 35, wherein the alignment device is affixed to skin of the patient.

80. The method of claim 35, wherein the alignment device is bonded to the patient.

81. The method of claim 35, wherein the alignment device is planar.